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EXAMINER

KUMAR, VINOD

ART UNIT

PAPER NUMBER

1638

NOTIFICATION DATE

DELIVERY MODE

12/27/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/556,669	BRESSAN, RAY A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	VINOD KUMAR	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/14/2006</u>   | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### **Election/Restrictions**

1. Applicant's election without traverse of Group I (Claims 1-19 and 22-23) in the reply filed on 9/29/2010 is acknowledged.

Claims 20-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Accordingly, claims 1-19 and 22-23 are examined on merits in this Office action. This restriction is made FINAL.

### **Information Disclosure Statement**

2. An initialed and dated copy of Applicant's IDS form 1449 filed on 2/14/2006 is attached to the instant Office action. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### **Specification**

The disclosure is objected to because of the following informalities:

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. For example, description of drawings do not have SEQ ID listed with the sequences. Amino acid sequences in Figure 6C must be referred to by their sequence identifiers.

If the sequences appearing in the specification do not have sequence ID numbers assigned to them, then an amendment to the sequence listing will be required as well. There

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must not be any new matter submitted, therefore it is important to be careful to include only the sequences that are already disclosed in the current specification.

### **Claim Objections**

4. Claims 1, 2, 5, 7-9, 11, 12, 16-19 and 22 are objected to because of the following informalities:

Claims 1 and 22 are objected for having improper article before “amino acid sequence” in line 3. It is suggested to change “an” to --the--.

Claim 2 is objected for having improper article before “nucleotide” in line 1. It is suggested to change “a” to --the--.

Claims 5, 7, 9, 16, 17 and 18 are objected for having space between “HOS” and “10”. It is suggested to change “HOS 10” to --HOS10-- to maintain consistency.

Claim 8 is objected for misspelling “HOSIO”. It is suggested to change “HOSIO” to --HOS10--.

Claim 8 is objected for reciting “a HOSIO protein (SEQ ID NO: 1)”. It is suggested to change “a HOSIO protein (SEQ ID NO: 1)” to --a HOS10 protein as set forth in SEQ ID NO: 1--.

Claims 8, 11, 17 and 19 are objected for reciting “comprising” in line 1. The recitation “comprising” reads on any transgenic Arabidopsis cell or plant which would inherently comprise a nucleic acid sequence encoding HOS10 polypeptide of SEQ ID NO: 1. That does not appear to be Applicant’s intention. It is suggested to change “comprising” to --transformed with--.

Claim 12 is objected for reciting “an HOS10 polypeptide (SEQ ID NO: 2)”. It is suggested to change “an HOS10 polypeptide (SEQ ID NO: 2)” to --a HOS10 polypeptide as set

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forth in SEQ ID NO: 1--. It may be noted that SEQ ID NO: 1 is a polypeptide, whereas SEQ ID NO: 2 is a polynucleotide sequence.

Claims 16-18 are objected for reciting “an HOS 10 polypeptide (SEQ ID NO: 1)”. It is suggested to change “an HOS 10 polypeptide (SEQ ID NO: 1)” to --a HOS10 polypeptide as set forth in SEQ ID NO: 1--.

Claims 19 is objected for reciting “an HOS10 polypeptide (SEQ ID NO: 1)”. It is suggested to change “an HOS10 polypeptide (SEQ ID NO: 1)” to --a HOS10 polypeptide as set forth in SEQ ID NO: 1--.

Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because claims 12 and 22 are incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The preamble says a method of improving response of a plant to stress, wherein the last recited method step comprises adding and expressing a DNA molecule. The last method step does not mention whether the plant's response to stress is improved or not. The last method step does not mention whether the plant is transformed. It is important to note that adding a DNA molecule to a plant does not necessarily

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result in the plant transformation. It is unclear which active method steps are required to practice the instantly claimed method.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation “a transcription factor in a different pathway than HOS 10”, which is confusing since it is unclear which “different pathway” is being referred to. It is unclear how the recited “a transcription factor” is different than “HOS10”. It is unclear what is intended.

Claims 8, 12 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in reciting a recitation within parenthesis, since it is unclear whether the recitation within the parenthesis is a part of the claim limitation. See claim objections for suggested amendments.

Dependent claims are also rejected because they fail to overcome the deficiency of parent claims.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4, 6-7, 11 and 22-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling a method of improving stress response in a plant, comprising transforming a plant with a DNA molecule encoding SEQ ID NO: 1, or a transformed plant and seed comprising said DNA molecule, does not reasonably provide enablement for a DNA molecule encoding a polypeptide having 90% identity to SEQ ID NO: 1, and making a stress tolerant plant comprising expressing SEQ ID NO: 1 in any manner other

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than transforming a plant with a nucleotide sequence encoding SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the Wands factors. In re Wands, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). In re Wands lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Claims are broadly drawn to a method for improving response of a plant to stress, the method comprising: (a) adding a DNA molecule, whose nucleotide sequence encodes a polypeptide that is at least 90% identical to an amino acid sequence as in SEQ ID NO: 1 to the plant; and (b) expressing the DNA molecule in a plant, or wherein the DNA molecule comprises a nucleotide sequence as in SEQ ID NO: 2, or wherein the DNA molecule is stably integrated in the plant genome, or wherein the stress is selected from the group consisting of cold, osmotic stress, drought, and abscisic acid, or wherein the polypeptide is an Arabidopsis thaliana HOS10 transcription factor as in SEQ ID NO: 1, or wherein the plant is a monocot, or wherein the method further comprising adding at least one other DNA molecule that encodes a transcription factor in a different pathway than HOS10, or a plant seed comprising a recombinant nucleic acid molecule encoding a polypeptide comprising an amino acid sequence that is at least

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90% identical to SEQ ID NO: 1, or a method for improving response of a plant to stress, the method comprising: (a) adding a DNA molecule, whose nucleotide sequence encodes a polypeptide that is at least 90% identical to an amino acid sequence as in SEQ ID NO: 1 to the plant; and (b) expressing the DNA molecule in a plant under a tissue specific promoter, or wherein, the tissue specific promoter is selected from the group consisting of root, flower, fruit, leaves, stem, and petiole specific promoters.

Claims 1, 11 and 22 are directed to a polynucleotide that encodes a polypeptide having at least 90% identity to SEQ ID NO: 1.

The instant specification provides guidance on making a transgenic plant with cold tolerant phenotype comprising over-expression of a nucleotide sequence encoding HOS10 protein of SEQ ID NO: 1. See in particular, pages 11-12, examples 1-2; table 1.

The specification does not teach making transgenic plants exhibiting increased stress tolerance by over-expressing a polynucleotide encoding a polypeptide having 90% identity to SEQ ID NO: 1.

The claims encompass a polypeptide having unspecified changes in the amino acid sequence of SEQ ID NO: 1.

Thus, from the guidance in the specification, it would appear that the vast majority of the amino acids in SEQ ID NO: 1 could be changed with any other amino acid.

The instant specification fails to provide guidance for which amino acids of SEQ ID NO: 1 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain the functional activity of the encoded protein. The specification also fails to provide



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guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein that functions as a stress tolerant protein.

Making changes in the amino acid sequence of SEQ ID NO: 1 protein is unpredictable. While it is known that many amino acid substitutions, additions or deletions are generally possible in any given protein the positions within the protein's sequence where such amino acid changes can be made with a reasonable expectation of success (without altering protein function) are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These regions can tolerate only relatively conservative substitutions or no substitutions (see for example, Wells, *Biochemistry* 29:8509-8517, 1990, see pages 8511-8512, tables 1-2; Ngo et al., pp. 492-495, 1994, see page 491, 1<sup>st</sup> paragraph).

Also, see Guo et al. (*PNAS*, 101: 9205-9210, 2004, see page 9205, abstract; page 9206, table 1; page 9208, figure 1) who teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as the claims encompass more than a single amino acid changes in the sequence of SEQ ID NO: 1.

Also see, Keskin et al. (*Protein Science*, 13:1043-1055, 2004, see page 1043, abstract) who teach that proteins with similar structure may have different functions. Furthermore, Thornton et al. (*Nature structural Biology*, structural genomics supplement, November 2000, page 992, 2<sup>nd</sup> paragraph bridging columns 1 and 2) teach that structural data may carry information about the biochemical function of the protein. Its biological role in the cell or

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organism is much more complex and actual experimentation is needed to elucidate actual biological function under in vivo conditions.

The state of the art related to the expression of transcription factor in a transgenic plant environment produces unexpected results. See for example, Yang et al. (PNAS, 98:11438-11443, 2001; abstract; pages 11442-11443) who teach that transgenic rice plants constitutively overexpressing REB transcription factor resulted in sterile transgenic plants.

See also McConnell et al. (Nature, 411:709-713, 2001; see in particular, abstract; figure 2) who teach that a single amino acid change (glycine to aspartic acid) in START domain of either PHABULOSA or PHAVOLUTA (homeodomain leucine zipper domain containing transcription factor) was sufficient to alter sterol/lipid binding domain activity.

Thus, making and analyzing proteins with large and unspecified amino acid changes and that function as stress tolerant protein(s) would require undue experimentation.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids encoding proteins having large and unspecified changes in the amino acid sequence of SEQ ID NO: 1.

Thus in the absence of adequate guidance from the specification, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those that function as a stress tolerant, if such plants are even obtainable.

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Additionally, claims encompass increasing stress tolerance in a plant using any method of expressing SEQ ID NO: 1. The specification provides guidance on making a cold tolerant plant by transforming and overexpressing a polynucleotide encoding SEQ ID NO: 1. But specification does not provide guidance on making a stress tolerant plant comprising overexpressing SEQ ID NO: 1 in any manner other than transforming a plant with a nucleotide sequence encoding SEQ ID NO: 1.

The specification does not provide guidance on co-factors, or positive regulators of SEQ ID NO: 1 for example that makes the gene encoding SEQ ID NO: 1 to overexpress to produce a stress tolerant plant. The specification provides no guidance on up-stream regulatory factors, for example, that may be necessary in stimulating the overexpression endogenous SEQ ID NO: 1. In the absence of guidance, undue experimentation would have been required by a skilled artisan to determine how a stress tolerant plant could have been produced by a method that comprises overexpression of SEQ ID NO: 1 without transforming the plant with a polynucleotide encoding SEQ ID NO: 1.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention commensurate in scope with these claims.

7. Claims 1, 3-4, 6-7, 11, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

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Claims are broadly drawn to a method for improving response of a plant to stress, the method comprising: (a) adding a DNA molecule, whose nucleotide sequence encodes a polypeptide that is at least 90% identical to an amino acid sequence as in SEQ ID NO: 1 to the plant; and (b) expressing the DNA molecule in a plant, or wherein the DNA molecule is stably integrated in the plant genome, or wherein the stress is selected from the group consisting of cold, osmotic stress, drought, and abscisic acid, or wherein the plant is a monocot, or wherein the method further comprising adding at least one other DNA molecule that encodes a transcription factor in a different pathway than HOS10, or a plant seed comprising a recombinant nucleic acid molecule encoding a polypeptide comprising an amino acid sequence that is at least 90% identical to SEQ ID NO: 1, or a method for improving response of a plant to stress, the method comprising: (a) adding a DNA molecule, whose nucleotide sequence encodes a polypeptide that is at least 90% identical to an amino acid sequence as in SEQ ID NO: 1 to the plant; and (b) expressing the DNA molecule in a plant under a tissue specific promoter, or wherein, the tissue specific promoter is selected from the group consisting of root, flower, fruit, leaves, stem, and petiole specific promoters.

The essential feature of claims 1, 11 and 22 is a DNA molecule that encodes a polypeptide having 90% identity to SEQ ID NO: 1.

The claims encompass a polypeptide having unspecified changes in the amino acid sequence of SEQ ID NO: 1.

The instant specification describes SEQ ID NO: 2 and its encoded protein of SEQ ID NO: 1 which has cold tolerant property upon over-expression in a plant. See in particular, pages 11-12, examples 1-2; table.

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The specification does not describe structure for a representative species of Applicant's broadly claimed genus and thus their function is unknown.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of functional activity (increased or improved stress tolerance) of SEQ ID NO: 1.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs: 1 and 2 are insufficient to describe the claimed genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 8-19 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexandrov et al. (EP 1033405 A2, Published June 9, 2000) taken with the evidence of Zhu et al. (PNAS, 102:9966-9971, 2005).

Claims are broadly drawn to a method for improving response of a plant to stress, the method comprising: (a) adding a DNA molecule, whose nucleotide sequence encodes a polypeptide that is at least 90% identical to an amino acid sequence as in SEQ ID NO: 1 to the plant; and (b) expressing the DNA molecule in a plant, or wherein the DNA molecule comprises a nucleotide sequence as in SEQ ID NO: 2, or wherein the DNA molecule is stably integrated in the plant genome, or wherein the stress is selected from the group consisting of cold, osmotic stress, drought, and abscisic acid, or wherein the polypeptide is an *Arabidopsis thaliana* HOS10 transcription factor as in SEQ ID NO: 1, or wherein the plant is a monocot, or a transgenic plant comprising a recombinant nucleic acid encoding a HOS10 protein (SEQ ID NO: 1), wherein an increased expression of the protein within the plant results in increased cold resistance to the plant, or wherein the transgenic plant has the HOS10 protein having an amino acid sequence comprising SEQ ID NO: 1, or wherein the transgenic plant is a monocot, or a plant seed comprising a recombinant nucleic acid molecule encoding a polypeptide comprising an amino acid sequence that is at least 90% identical to SEQ ID NO: 1, or an expression cassette comprising a promoter functional in a plant cell operably linked to an isolated nucleic acid sequence encoding an HOS10 polypeptide (SEQ ID NO:2), wherein an enhanced expression of the polypeptide in the plant cell results in increased cold resistance to the plant, or wherein the promoter of the expression cassette is stress induced, or wherein the stress induced promoter is

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selected from the group consisting of an ABA-inducible promoter, a turgor-inducible promoter, or wherein the promoter is selected from the group consisting of a viral coat protein promoter, a plant tissue-specific promoter, a monocot promoter, a ubiquitin promoter, a CaMV 35S promoter, a CaMV 19S promoter, a nos promoter, an Adh promoter, a sucrose synthase promoter, a tubulin promoter, a napin promoter, an actin promoter, a cab promoter, a PEP Case promoter, a 7S $\alpha$ -conglycinin promoter, an R gene complex promoter, a tomato E8 promoter, a patatin promoter, a mannopine synthase promoter, a soybean seed protein glycinin promoter, a soybean vegetative storage protein promoter, a bacteriophage SP6 promoter, a bacteriophage T3 promoter, a bacteriophage T7 promoter, a Ptac promoter, and a root-cell promoter, or a plant vector comprising a recombinant nucleic acid encoding a HOS10 polypeptide (SEQ ID NO: 1), wherein an expression of the polypeptide in a plant results in increased cold resistance to the plant, or an host plant cell comprising a recombinant nucleic acid encoding a HOS10 polypeptide (SEQ ID NO: 1), wherein an expression of the polypeptide in a plant results in increased cold resistance to the plant, or a plant vector comprising a recombinant nucleic acid encoding a HOS10 polypeptide (SEQ ID NO: 1), wherein an expression of the polypeptide in a plant results in increased salt resistance to the plant, or a host plant cell comprising a recombinant nucleic acid encoding a HOS10 polypeptide (SEQ ID NO: 1), wherein an expression of the polypeptide in a plant results in increased salt resistance to the plant, or a method for improving response of a plant to stress, the method comprising: (a) adding a DNA molecule, whose nucleotide sequence encodes a polypeptide that is at least 90% identical to an amino acid sequence as in SEQ ID NO: 1 to the plant; and (b) expressing the DNA molecule in a plant under a tissue specific promoter,



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or wherein, the tissue specific promoter is selected from the group consisting of root, flower, fruit, leaves, stem, and petiole specific promoters.

Alexandrov et al. disclose a method of producing a transgenic plant cell comprising transformation of said plant cell with a plant transformation vector comprising an expression cassette which comprises a nucleic acid sequence (SEQ ID NO: 67644, identical to instant SEQ ID NO: 2) encoding a polypeptide (SEQ ID NO: 67645) which is identical in sequence to instant SEQ ID NO: 1. The reference further discloses that the vector which comprises a gene construct having an expression cassette which comprises said nucleic acid sequence is operably linked to a promoter (constitutive, tissue-specific or inducible) which is inherently capable of causing transcription in a plant cell (see pages 22-23, and 327-329), and wherein said promoter is either native or heterologous (non-native) to the nucleic acid sequence disclosed in the reference. The reference further discloses that said promoter is a stress-inducible promoter, such as ABA-inducible or ethylene responsive promoter. The reference also discloses that said promoter is a tissue specific promoter, such as a root-specific or leaf specific promoter. The reference also discloses that said promoter is a CAMV 35S promoter, and wherein said plant is a dicot or monocot plant species. The reference further discloses regenerating a transgenic plant from said transformed plant cell. The reference also discloses transgenic plants over-expressing the nucleic acid sequence encoding the polypeptide disclosed in the reference. The reference further discloses that said transgenic plant is rapeseed, or soybean (dicot and legume). The reference also discloses producing transgenic seeds from said transgenic plant. The reference further discloses that SEQ ID NO: 67645 is a HOS10 (high response to osmotic stress) transcription factor. The reference also discloses stably incorporating the expression cassette in transgenic

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plants and then introducing into other plants by sexual crossing using standard breeding techniques. See paragraph 2307 at page 329. It may be noted that propagating transgenic plants through sexual crossing would inherently comprise obtaining transgenic seeds. See in particular, claims 1-34, pages 327- 335, 341-343, and SEQ ID NOs: 67644 and 67645.

Although Alexandrov et al. do not explicitly disclose increased stress (e.g. cold) tolerance property of their transgenic plants or seeds derived thereof, such property would be inherent to the transgenic plant comprising over-expressing Alexandrov et al. polypeptide of SEQ ID NO: 6745 (identical in sequence to instant SEQ ID NO: 1, emphasis added) in Alexandrov et al. transgenic plant or seeds derived thereof, unless the Applicant provides evidence to the contrary.

The inherent property of improved cold tolerance in Alexandrov et al. plants overexpressing by SEQ ID NO: 6745 is also evidenced by Zhu et al., who describe making transgenic plants overexpressing a polypeptide which is identical in sequence to instant SEQ ID NO: 1 and exhibiting improved cold tolerance. See in particular, page 9966, abstract; page 9967, figure 1; page 9968, figures 2-4; page 9969, figures 5-6.

See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343,1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) where a claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase “rich in glucosinolates” helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently “rich in glucosinolates”).

Also see *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif

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1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

It may also be emphasized that something which is old does not become patentable upon the discovery of a new property. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See also *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01.

Accordingly, Alexandrov et al. anticipated the claimed invention.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alexandrov et al. (EP 1033405 A2, Published June 9, 2000).

Alexandrov et al. teach a method of producing a transgenic plant cell comprising transformation of said plant cell with a plant transformation vector comprising an expression cassette which comprises a nucleic acid sequence (SEQ ID NO: 67644, identical to instant SEQ

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ID NO: 2) encoding a polypeptide (SEQ ID NO: 67645) which is identical in sequence to instant SEQ ID NO: 1. The reference further teaches that the vector which comprises a gene construct having an expression cassette which comprises said nucleic acid sequence is operably linked to a promoter (constitutive, tissue-specific or inducible) which is inherently capable of causing transcription in a plant cell (see pages 22-23, and 327-329), and wherein said promoter is either native or heterologous (non-native) to the nucleic acid sequence taught in the reference. The reference further teaches that said promoter is a stress-inducible promoter, such as ABA-inducible or ethylene responsive promoter. The reference also teaches that wherein said promoter is a tissue specific promoter, such as a root-specific or leaf specific promoter. The reference also teaches that said promoter is a CAMV 35S promoter, and wherein said plant is a dicot or monocot plant species. The reference further teaches regenerating a transgenic plant from said transformed plant cell. The reference also teaches transgenic plants over-expressing the nucleic acid sequence encoding the polypeptide disclosed in the reference. The reference further teaches that said transgenic plant is rapeseed, or soybean (dicot and legume). The reference also teaches producing transgenic seeds from said transgenic plant. The reference further teaches that SEQ ID NO: 67645 is a HOS10 (high response to osmotic stress) transcription factor. The reference also teaches stably incorporating the expression cassette in transgenic plants and then introducing into other plants by sexual crossing using standard breeding techniques. See paragraph 2307 at page 329. It may be noted that propagating transgenic plants through sexual crossing would comprise obtaining transgenic seeds. See in particular, claims 1-34, pages 327- 335, 341-343, and SEQ ID NOs: 67644 and 67645.

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Alexandrov et al. do not teach transforming the transgenic plant overexpressing SEQ ID NO: 67645 with an another nucleic acid encoding a different transcription factor.

It would have been obvious and within the scope of an ordinary skill in the art to have transformed stress tolerant transgenic plant overexpressing HOS10 polypeptide of SEQ ID NO: 67645 with an additional recombinant polynucleotide encoding a different and unrelated transcription factor of Alexandrov et al. (for example, a DOF-type zinc finger domain containing transcription factor, transcription factors involved in disease resistant cited in the reference) to arrive at the claimed invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to do so for the purpose of imparting stress tolerance to environmental stress responsive factors other than cold, osmotic stress, drought or abscisic acid in the transgenic plant overexpressing Alexandrov et al. protein with a reasonable expectation of success.

### **Conclusions**

10. Claims 1-19 and 22-23 are rejected.

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Vinod Kumar/  
Primary Examiner, Art Unit 1638